UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

ADAM KANUSZEWSKI, et al.,

Plaintiffs,

v.

SANDIP SHAH, et al.,

Defendants.
_____/

Case No. 1:18-cv-10472

Honorable Thomas L. Ludington
United States District Judge

OPINION AND ORDER DENYING DEFENDANTS' *DAUBERT* MOTION

Defendants filed a motion to exclude the expert testimony of Dr. Elizabeth Eisenhauer and Professor Sonia Suter. ECF No. 143. As explained hereafter, Defendants' Motion will be denied.

I.

This case involves a § 1983 action arising from alleged constitutional violations concerning Michigan's Newborn Screening Program (NSP). Under the NSP, which Michigan has operated since the 1960s, the State of Michigan and its agents prick the heel of nearly every newborn to collect a blood sample with a Dried Blood Spot (DBS) collection card.[1] *Kanuszewski v. Mich. Dep't of Health & Hum. Servs.*, 927 F.3d 396, 403–04 (6th Cir. 2019). The State of Michigan purportedly uses the babies' blood for "medical" and "health" research on its population and to identify victims and perpetrators of crimes, in addition to selling babies' blood to private entities for a substantial, undisclosed profit. *See generally id.*; *see also* ECF No. 148 at PageID.4847.

[1] In the scientific community, this procedure is called a "neonatal heel prick," and the cards are called "Guthrie cards." Tufik Y. Shayeb, *Informed Consent for the Use and Storage of Residual Dried Blood Samples from State-Mandated Newborn Genetic Screening Programs*, 64 BUFF. L. REV. 1017, 1020 & n.16 (2016).

Currently, Michigan law requires testing of all newborns for phenylketonuria, galactosemia, hypothyroidism, maple syrup urine disease, biotinidase deficiency, sickle cell anemia, congenital adrenal hyperplasia, medium-chain acyl-coenzyme A dehydrogenase deficiency, and "[o]ther treatable but otherwise disabling conditions as designated by the department." MICH. COMP. LAWS § 333.5431(1). According to the Michigan Department of Health and Human Services (MDHHS), Michigan tests for over 50 disorders and diagnoses about 0.2–0.25% of Michigan's newborns with one of the rare disorders. *See* ECF No. 147-2 at PageID.4243.

On February 8, 2018, Plaintiffs Shannon LaPorte,[2] Adam and Ashley Kanuszewski, and Lynette Wiegand, individually and as parent-guardians of their minor children, sued the MDHHS, Nick Lyon (the then-Director of the MDHHS), Dr. Sandip Shah (the Director of the Bureau of Laboratories), Dr. Sarah Lyon-Callo (a state epidemiologist), Mary Kleyn (the Manager of the Newborn Screening Section), Michigan Neonatal Biobank, Inc., and Dr. Antonio Yancey (the Director of the Michigan Neonatal Biobank). ECF No. 3.

Plaintiffs' Complaint alleges that Defendants violated Plaintiffs' Fourteenth Amendment (substantive due process) rights by extracting blood from their babies then storing and using the blood spots without their constitutionally adequate consent (Counts I and II). ECF No. 26 at PageID.322–25. Plaintiffs also allege that Defendants violated their Fourth Amendment rights (against unreasonable searches and seizures) by extracting the blood (Count III) and by indefinitely storing the blood spots (Count IV). *See id.* at PageID.325–29.[3]

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[2] On April 4, 2020, the case was consolidated with *LaPorte v. Gordon*, No. 1:20-CV-10089 (E.D. Mich. Apr. 29, 2020). *See* ECF No. 104. However, the *LaPorte* Plaintiffs have since voluntarily dismissed their claims from that case. *See* ECF Nos. 114; 116; 118; 120.

[3] *See generally* Laura Beth Cohen, *Informing Consent: Medical Malpractice and the Criminalization of Pregnancy*, 116 MICH. L. REV. 1297, 1304 (2018) (discussing the implications of informed consent for medical procedures in the context of the Fourth and Fourteenth Amendment); Margaret A. Berger & Aaron D. Twerski, *Uncertainty and Informed Choice: Unmasking* Daubert, 104 MICH. L. REV. 257, 270 (2005) ("The right of a patient to informed

Defendants filed separate motions to dismiss. ECF Nos. 32, 33, 34. Those motions were granted, and the complaint was dismissed. *See generally Kanuszewski v. Mich. Dep't of Health & Hum. Servs.*, 333 F. Supp. 3d 716 (E.D. Mich. 2018).

On August 8, 2018, Plaintiffs appealed the dismissal to the Sixth Circuit Court of Appeals. ECF No. 52. Ten months later, the Sixth Circuit affirmed and reversed in part, remanding two claims for further proceedings: first, Plaintiff-parents' substantive-due-process claim for the storage of the blood samples, seeking injunctive and declaratory relief (Count II); and second, the Plaintiff-children's Fourth Amendment claim for the storage of the blood samples, seeking injunctive and declaratory relief (Count IV). *Kanuszewski*, 927 F.3d 396; ECF No. 78. After remand, the case proceeded as normal for nearly 21 months. *See* ECF Nos. 79–142.

On March 24, 2021, Defendants filed a Motion to Exclude Expert Testimony, ECF No. 143, which the parties have fully briefed, ECF Nos. 148; 154.

II.

Relying on the seminal *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), Defendants seek to exclude the testimony of Plaintiffs' experts as "not reliable or helpful," claiming "both of their testimony is based on insufficient facts or data." ECF No. 143 at PageID.3381.

A.

Federal Rule of Evidence 702 governs the admissibility of expert testimony, providing that:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and

consent has been a staple of U.S. medical malpractice law for [nearly five] decades.").

> (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702.

Rule 702 assigns the district court "the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand"—a kind of "gatekeeping role." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). In this role, district courts consider several factors that the *Daubert* Court identified, including whether the expert's methods are testable and subject to peer review. *Id.* at 593–94; *see also United States v. Bonds*, 12 F.3d 540, 558 (6th Cir. 1993) (identifying and discussing the so-called "*Daubert* factors").

The *Daubert* factors "do not constitute 'a definitive checklist or test" and do not apply in every case. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999). "Rather, the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination." *Id.* at 142; *see also Surles ex rel. Johnson v. Greyhound Lines, Inc.*, 474 F.3d 288, 295 (6th Cir. 2007) ("The gatekeeping inquiry is context-specific and 'must be tied to the facts of a particular case.'") (quoting *Kumho Tire*, 526 U.S. at 142).

The qualifications of Dr. Elizabeth R. Eisenhauer will be discussed first, *infra* Section II.B, followed by the qualifications of Professor Sonai M. Suter, *infra* Section II.C, and then the scope of their testimony, *infra* Section II.D.

B.

Defendants seek to preclude the testimony of Dr. Elizabeth R. Eisenhauer, Ph.D., R.N. ECF No. 143-1 at PageID.3393, 3398. As Defendants note, Plaintiffs will offer Dr. Eisenhauer's "opinion regarding informed consent and biobanking formed on the basis of one qualitative study." ECF No. 143 at PageID.3382.

Doctor Eisenhauer has the knowledge and education to testify about biobanking and informed consent. FED. R. EVID. 702. For years, she researched the "ethical, legal, and social implications of biobanking and genetic testing, specifically related to informed consent." ECF No. 143-1 at PageID.3393. Moreover, she earned a certificate in Health Informatics before earning a Ph.D. in Nursing for defending her doctoral dissertation, *Informed Choices in Biobanking*. *Id.* at PageID.3399, 3401. Then she published two peer-reviewed journal articles on biobanking and informed consent. *See id.* at PageID.3401. In sum, Dr. Eisenhauer is an expert in biobanking and informed consent.

Defendant only challenges Dr. Eisenhauer's testimony as not "based on sufficient facts or data." FED. R. EVID. 702(b); *see* ECF No. 143 at PageID.3385–86. Specifically, Defendant claims that the published study she relies on is statistically unreliable due to an insufficient sample size. *See* ECF No. 143 at PageID.3385–86.

Although qualitative, Dr. Eisenhauer's study uses a methodology called the multidimensional measure of informed choice (MMIC), relying on the "knowledge, attitudes, and participation" of a mother choosing whether "to donate their newborn's rDBS to the Michigan BioTrust for Health." ECF No. 143-1 at PageID.3406, 3412. She directly adopted the MMIC methodology from the highly published article that created it. *See* Theresa M. Marteau, Elizabeth Dormandy & Susan Michie, *A Measure of Informed Choice*, 4 HEALTH EXPECTATIONS 99 (2001) (developing "a measure of informed choice"). And at least 234 other articles have cited that article. *See* Nat'l Libr. of Med., *A Measure of Informed Choice*, NAT'L CTR. FOR BIOTECHNOLOGY INFO. (Jan. 29, 2022), https://pubmed.ncbi.nlm.nih.gov/11359540/ [https://perma.cc/VKL9-MFES]. Moreover, Dr. Eisenhauer's application of the MMIC is scientifically sound. *See* ECF No. 148 at PageID.4842–43.

Being grounded in reliable methodology, FED. R. EVID. 703, Dr. Eisenhauer's expert testimony will corroborate Plaintiffs-parents' experiences and help the trier of fact contrast their consent to participate in the NSP to other parents' informed consent. Indeed, based on her observational study, Dr. Eisenhauer's testimony will attempt to illustrate consistency between the lack of parental informed consent of Plaintiff-parents and other parents. Moreover, Plaintiffs offer her testimony to contradict Defendants' claims that Plaintiffs' consent was constitutionally adequate. And she will be relying on not only her personal knowledge but also her background knowledge. *Id.*

C.

Defendants also seek to preclude the testimony of Plaintiffs' expert Professor Sonia Mateu Suter, J.D., M.S. ECF No. 143-1 at PageID.3415. According to Defendants, Professor Mateu Suter "will provide an opinion regarding 'informed consent in newborn screening programs' and describe an 'alternative methodology' to balance 'the wellbeing of newborns . . . while also protecting autonomy and privacy as much as possible.'" ECF No. 143 at PageID.3382 (citation omitted). As Plaintiffs add, she intends to contrast the costs and benefits of an opt-out consent system to those of an opt-in system. ECF No. 148 at PageID.4846.

Professor Suter has the "knowledge, skill, experience, training, [and] education" to testify about the alternative methods of obtaining consent in a healthcare setting, specifically regarding the bioethical implications, law, and policy surrounding consent for genetics research. FED. R. EVID. 702. Indeed, before obtaining a Master of Science in Human Genetics and then earning the award for the highest grade in "Law, Medicine, and Bioethics" at the University of Michigan Law School, she was a Genetic Counselor in obstetrics and pediatrics for two years at Henry Ford Hospital. ECF No. 143-1 at PageID.3415–16. Later, she completed a two-year fellowship in

"Bioethics and Health Policy." *Id.* at PageID.3415. Now, she teaches "Genetics & Law" and "Law & Medicine" as the Kahan Family Research Professor of Law at George Washington University Law School. *See id.*; ECF Nos. 143 at PageID.3415; 148 at PageID.4845 & n.4. Moreover, among many other relevant experiences, she served for five years on the expert panel of the NSP at the American College of Medical Genetics. ECF No. 143-1 at PageID.3422. And through more than a third of a century, she has completed at least 97 presentations and peer-reviewed journal articles discussing, among other things, "Baby Markets," "Ethical Issues in Genetic Testing," and the "Duty to Warn" regarding "Legal Challenges in Genetics." *Id.* at PageID.3416–23. In other words, Professor Sonia M. Suter is an expert in the costs and benefits of alternative methods to obtain consent for genetic research.

Defendants contest Professor Suter's testimony as not "help[ful to] the trier of fact to understand the evidence or to determine a fact in issue."[4] FED. R. EVID. 702(a); *see* ECF No. 143 at PageID.3385–86. Specifically, Defendants contend that "as a law professor," she "does not possess scientific, technical, or other specialized knowledge that will assist the Court to understand evidence or determine a fact in issue." ECF No. 143 at PageID.3387. As explained, Professor Suter is much more than a mere law professor; she is a titan in her field. Moreover, district courts often allow law professors to testify about relevant norms and whether conduct falls within them. *See, e.g.*, *Pinal Creek Grp. v. Newmont Mining Corp.*, 352 F. Supp. 2d 1037, 1046 (D. Ariz. 2005).

Defendants also argue that Professor Suter's testimony regarding an alternative method to obtain consent should be excluded for "focus[ing] more on Plaintiffs' desired remedy than Plaintiffs' alleged injury." *Id.* at PageID.3387. But pending before this Court is not only Plaintiffs'

[4] Defendants also challenge Professor Suter's expert testimony as "not '[p]ertinent evidence based on scientifically valid principles." ECF No. 143 at PageID.3388 (citing *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993)). But Defendants offer nothing substantive to this claim. Therefore, this Court will not consider it.

motion for reconsideration of this Court's partial denial of summary judgment on their substantive-due-process claim regarding consent, but also Defendants' motion for reconsideration of this Court's finding that the "MDHHS has not shown that it followed the four requirements to ensure consent was received." ECF Nos. 172; 174 at PageID.5639. Because both parties still challenge the substantive aspects of consent as relevant to Plaintiffs' substantive-due-process claims, issues of fact remain regarding Plaintiffs' consent.

D.

Notably, due to timing, it is reasonable to assume that Plaintiffs' experts developed their testimony specifically for litigation, giving rise to concerns about reliability. *See Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 593–94 (1993); *Lust ex rel. Lust v. Merrell Dow Pharms.*, 89 F.3d 594, 597 (9th Cir. 1996). But as explained above, their methods were reliable and well recognized in the scientific community. *See* discussion *supra* Sections II.B, II.C. And Defendants have not offered any scientific evidence to counter the reliability of Plaintiffs' proposed experts. *See Lust*, 89 F.3d at 598. If another expert used the same professional standards but reached a different conclusion, this Court might reasonably suspect Plaintiffs' experts did not faithfully apply the principles and methods. Defendants have not even attempted to prove that case. The testimony of Plaintiffs' experts is therefore reliable.

Having established that Plaintiff's experts have a reliable basis for their testimony, Defendants' remaining concerns, including the insufficiency of empirical testing, are relevant to only the weight of the testimony and should be raised, if at all, on cross-examination. *See In re E. I. Du Pont De Nemours & Co. C-8 Pers. Inj. Litig.*, 337 F. Supp. 3d 728, 738 (S.D. Ohio 2015) (noting that the *Daubert* inquiry is "not intended to supplant the adversary system or the role of the jury" and that "[a]rguments regarding the weight to be given any testimony or opinions of an

expert witness are properly left to the jury" (citing *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 531–32 (6th Cir. 2008))).

Importantly, however, Plaintiffs' experts may not spoon-feed the jury conclusions it could reach on its own. Indeed, "testimony that does no more than 'tell the jury what result to reach . . . hardly can be viewed as being helpful to the jury.'" *Good v. BioLife Plasma Servs., L.P.*, No. 1:18-CV-11260, 2022 WL 188125, at *6 (E.D. Mich. Jan. 19, 2022) (quoting *Jesa Enters. v. Thermoflex Corp.*, 268 F. Supp. 3d 968, 973 (E.D. Mich. 2017)).

In the context of the Fourth and Fourteenth Amendments, it is well established that consent is an issue of fact. *United States v. Worley*, 193 F.3d 380, 384 (6th Cir. 1999) (collecting cases); *see Schneckloth v. Bustamonte*, 412 U.S. 218, 227 (1973) ("[W]hether a consent to a search was in fact 'voluntary' or was the product of duress or coercion, express or implied, is a question of fact to be determined from the totality of all the circumstances."); *accord United States v. Moon*, 513 F.3d 527, 537 (6th Cir. 2008) (quoting *Bustamonte*, 412 U.S. at 227); *see also United States v. Blomquist*, 976 F.3d 755, 758-59 (6th Cir. 2020) ("The government bears the burden of demonstrating by a preponderance of the evidence, through clear and positive testimony, that the consent was voluntary, unequivocal, specific, intelligently given, and uncontaminated by duress or coercion." (quoting *United States v. Alexander*, 954 F.3d 910, 918 (6th Cir. 2020))).

The same is true regarding the scope of consent. *See United States v. Garrido-Santana*, 360 F.3d 565, 570 (6th Cir. 2004).

As a guidepost, the Sixth Circuit has addressed the admissibility of expert testimony in the context of medical consent. In *Hanson v. Parkside Surgery Center*, a patient who was blinded in one eye during a radial keratotomy[5] brought a medical malpractice action against the performing

[5] A radial keratotomy is a medical procedure to correct nearsightedness. *Schachar v. Am. Acad. of Ophthalmology, Inc.*, 870 F.2d 397, 397 (7th Cir. 1989); *see also* Mark A. Hall & Carl E.

doctor. 872 F.2d 745 (6th Cir. 1989). The plaintiff-patient sought to admit expert testimony "on the issue of informed consent." *Id.* at 750. Specifically, the expert sought to testify whether a videotape that patients view as part of the informed-consent process improperly minimizes the procedure's risks. *Id.* Bifurcating the testimony, the district court permitted the expert to testify about what information was missing from the videotape, but it precluded him from testifying about "his belief that the tape presented the risks involved in the procedure in a 'persuasive' manner." *Id.* The district court bifurcated the testimony because the expert's expertise did not include "communications." *Id.*

This case is practically similar to *Hanson*. Although the grounds for the claim are different, the issue of consent is sufficiently analogous: When attempting to obtain consent, did the medical facility provide enough information about the procedure to render consent voluntary, or was the process impermissibly coercive?

The critical difference between *Hanson* and this case is that both Dr. Eisenhauer and Professor Suter have expertise in such "communications."

For more than six years, Doctor Eisenhauer has studied consent in the medical context, including the extent to which patients' ideological backgrounds affect such decisions. *See, e.g.*, Elizabeth R. Eisenhauer, Rsch. Assistant, Univ. of Mich. Sch. of Nursing, Poster Presentation of *Analysis of Content Coverage for Informed Consent Concepts* at the American Medical Informatics Association Annual Symposium (Nov. 16, 2014) (transcript available from the AMIA). Moreover, she conducted a qualitative study during which she observed Michigan's consent process. *See* Elizabeth R. Eisenhauer et al., *Mothers' Decisions About Donating Newborns' Blood Spots for Research*, 33 CONTINUING EDUC. 361 (2019). This study, and other

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Schneider, *Patients as Consumers: Courts, Contracts, and the New Medical Marketplace*, 106 MICH. L. REV. 643, 659 n.75 (2008).

aspects of her background, will help the jury understand the early stages of Michigan's biobanking system, including what could happen and has happened in an examination room. And though she did not observe Plaintiffs' consent, her testimony will aid the jury in contrasting Plaintiffs' experiences with those of other parents, providing a better understanding of the context of Plaintiffs' consent.

Similarly, Professor Suter has been studying consent in the context of medical decisions for nearly a decade. *See* Sonia M. Suter, *The Politics of Information, Informed Consent in Abortion and End-of-Life Decision Making*, 39 AM. J.L. MED. 7 (2013). And her focus on bioethics only makes her testimony even more unique and therefore valuable to the jury. Indeed, Professor Suter could succinctly translate the complex background and history of biobanking systems and survey the costs and benefits of biobanking, which will undoubtedly assist the jury.

For these reasons, Dr. Eisenhauer will be permitted to testify about biobanking and informed consent, and Professor Suter will be permitted to testify about informed consent and alternative methodologies that hospitals might use to obtain consent for genetic research. Neither expert may testify about whether Plaintiffs gave constitutionally or legally adequate consent, but they may "state opinions that suggest the answer to the ultimate issue or that give the jury all the information from which it can draw inferences as to the ultimate issue." *United States v. Maya*, 966 F.3d 493, 506 (6th Cir. 2020) (cleaned up) (quoting *United States v. Volkman*, 797 F.3d 377, 382 (6th Cir. 2015)); *see also Hygh v. Jacobs*, 961 F.2d 359, 363 (2d Cir. 1992) (collecting cases).

Consequently, Defendant's *Daubert* Motion will be denied, and Dr. Eisenhauer and Professor Suter will be permitted to testify consistent with this Opinion and subject to further order of this Court.

III.

Accordingly, it is **ORDERED** that Defendants' Motion to Exclude Expert Testimony, ECF No. 143, is **DENIED**.

Dated: February 3, 2022

s/Thomas L. Ludington
THOMAS L. LUDINGTON
United States District Judge